EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**No. 1:19-md-2875-RBK**

EXPERT DECLARATION OF RON NAJAFI, PH.D.

I. EXECUTIVE SUMMARY

1. I have been retained by plaintiffs' counsel to provide an opinion on whether Valsartan which contains NDMA or NDEA is the same and/or chemical equivalent of the Reference Listed Products, Diovan and/or Exforge.

2. When forming the opinions I express in this declaration, I employed methodologies used by chemists and pharmaceutical companies to comply with pre-approval and post-approval FDA obligations as well as current Good Manufacturing Practices ("cGMP"). My opinions are also based on FDA guidance and regulations as well as industry standards, and my practice and experience. These methodologies used in formation of my opinions are also used by Emery Pharma in making recommendations to our pharmaceutical clients.

3. As discussed more fully below, based on my education, training, and experience, the presence of the nitrosamine contamination found in the Valsartan products at issue here renders these products as not the same as the Reference Listed Drug, Diovan and/or Exforge.

4. The opinions I provide in this declaration are expressed with a reasonable degree of scientific certainty based on the information I have been provided to date for the purposes of this declaration, and I reserve the right to modify my opinions upon further review of additional information.

II. QUALIFICATIONS AND EXPERIENCE

5. I received my B.S. and M.S. in Organic Chemistry from the University of San Francisco in June of 1983. During my time at the University of San Francisco, I also held a position as a Teaching Assistant for Organic Chemistry Lab from 1982 to 1983. While studying at the University, I authored "The Hydroboration of Alkenyl Metalloids" which I presented at the 32nd Annual ACS Northern California Regional Undergraduate Research Conference. That same year I was the recipient of the University of San Francisco, Student Affiliates of the American Chemical Society Award for Outstanding Achievement in Chemistry. In March of 1983 I also authored "Selective Oxidation of Organoboranes with Anhydrous Trimethylamine N-Oxide" which was presented at the 185th National Meeting of the American Chemical Society in Seattle, Washington, as well as the 8th ACS Senior Technical Meeting in 1984 at the University of San Francisco.

6. In December of 1988, I received my Ph.D. in Organic Chemistry from the University of California, Davis. While attending University of California, I worked as an Associate-Instructor and Teaching Assistant for Advanced Organic Synthesis and supervised undergraduate students in general and organic chemistry labs from 1983 to 1988. While studying at the University of California, I authored "Stereoselective Syntheses of Alkenyl-Substituted 1,3-Dioxolanes or 4,7-Dihydro-1,3 dioxepins or an (E)-a,b-Unsaturated Aldehyde from (Z)-2-Butene-1,4-diols" in the Journal or Organic Chemistry in 1985. In 1987, I was the recipient of the University of California, Dow Chemical Company Graduate Teaching Assistant Award in Recognition of Outstanding Graduate Accomplishments. In 1988, I published "Hydroboration of Methoxyenynes. A Novel Synthesis of (E)-Methoxyenones" in Tetrahedron Letters. Also in 1988, I was the recipient of the University of California Campus-Wide Teaching Award for Outstanding Graduate Students.

7. I have been a member of the American Chemical Society since 1979 as well as an Associate Member of Sigma Xi a National Scientific Honor Society since 1988. I was the Secretary of the Philadelphia Organic Chemist Club from 1993 to 1994.

8. I was also the Co-Founder of Vision in Chemistry Annual Symposium at Rhone Poulenc Rorer (now Sanofi-Aventis) from 1991 to present day.

9. In addition to my academic positions, I have held several scientific roles at companies such as Rhone Poulenc Rorer (now Sanofi-Aventis), Applied Biosystems – a division of Perkin Elmer (now Thermo Fisher), and Aldrich Chemical Company (now Millipore Sigma). My work surrounding the study of chemistry has been widely recognized by those in the scientific community. In 1995 I was the recipient of Perkin-Elmer/Applied Biosystems President's Award for Innovative Discoveries in Chemistry amongst 1300 PhD's. These roles helped me develop extensive experience in all aspects of pharmaceutical and chemical development, spanning from the R&D stage to pilot plant manufacturing and beyond.

10. I have founded three companies of my own. From 1996 to 2002, I was President and CEO of CP Lab Safety, a company focused on environmental laboratory safety. In 2007, CP Lab Safety was the recipient of the Congressional Certificate of Environmental Sustainability from Congressman Jared Huffman. In 2000, I founded NovaBay Pharmaceuticals, Inc., a pharmaceutical company centered on developing non-antibiotic antimicrobial therapies. In 2008, I took the company public and continued to serve as the President and CEO until 2015. In 2007 I

was named Biotech Entrepreneur of the year by East Bay Business Journal. In 2011, I founded Najafi Pharma Inc., dba: Emery Pharma, where I currently serve as Chairman and CEO. To date I have authored over 20 publications relating to the study of chemistry and hold over 70 patents and pending patent applications on novel inventions. Emery Pharma is FDA registered and Inspected, cGMP / GLP compliant Contract Research Laboratory. Our mission is to help Save Lives and Save the Environment. Our team of eight (8) Ph.D. Chemists and Biologists help Pharmaceutical companies develop drugs following stringent regulatory guidance (FDA, ICH, USP, etc.).

11. A true and correct copy of my Curriculum Vitae is provided as Attachment "A" to this report that includes all publications on which I am listed as an author. My rate of compensation is $650 per hour. I have not testified in any deposition or trial over the last 4 years.

12. My career started as a development chemist at Aldrich Chemical Company where I had hands-on experience in cGMP synthesis of various precursors of Active Pharmaceutical Ingredients (API). Later at Rhone Poulenc Rorer Pharmaceutical (now Sanofi Aventis), I worked as a Process Chemist where we aimed to scale up pharmaceutically active compounds into Pilot Plant and later into a manufacturing facility and continuously were aware of the synthetic pathway, as well as evaluate many of the possible side reactions and potential impurities in the process. Next, at Applied Biosystems, I was given a task of finding why a DNA (a 20mer) synthesis was only 90% pure and contained a large amount of unknown impurity(ies). I was tasked to conduct a thorough root-cause analysis and find out the cause of the impurity. I was able to successfully discover a unique impurity in one of the key monomer components that was responsible for much of the impurity. This discovery resulted in "The Perkin-Elmer/Applied Biosystems President's Award for Innovative Discoveries in Chemistry amongst 1300 PhD's in 1995". In 1996 I left Applied Biosystems to form my own company (NovaBay Pharmaceuticals) around my own discovery of pure Hypochlorous Acid and NVC-422. In 2007, I took the company public and conducted multiple clinical trials in wound care, ophthalmology, common cold, Impetigo, etc. around the globe. In the process, I used various contract manufacturers to manufacture our medicine under cGMP and used the finished product to conduct multiple clinical trials under a FDA approved IND (Investigational New Drug application). In 2011 and 2014, we brought two products to market: NeutroPhase for wound care and Avenova for Blepharitis. I oversaw extensive stability studies where we also conducted shipping studies and elevated temperature studies

(accelerated stability study) to evaluate the viability of our drug substance and drug product and which was submitted to the FDA as part of our approval.

III. GENERAL RESPONSIBILITIES OF A DRUG COMPANY

13. It is the absolute responsibility of the drug manufacturer to provide a safe and effective drug product that meets quality standards.

14. Generic drugs are supposed to be the same as the brand-name drug, which in the case of Valsartan was Diovan or Exforge.

15. It was the drug manufacturers' responsibility to manufacture Valsartan to be the same, chemically equivalent and pass the same quality and purity standards as Diovan and/or Exforge.

16. As explained by the FDA, the main regulatory standard for ensuring pharmaceutical quality is the cGMPs regulation for human pharmaceuticals. The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients, purity and strength it claims to have.[1]

17. cGMPs provide for systems that assure proper design, monitoring, and control of manufacturing processes and facilities. It is imperative that drug manufacturers adhere to the cGMPs to assure the identity, strength, quality, and purity of drug products by requiring that manufacturers of medications adequately control manufacturing operations.

18. Generic drug manufacturers have an ongoing federal duty of sameness in their products.[2] The generic manufacturer must demonstrate that their active ingredient(s) are the same as the Reference Listed Drug("RLD")[3] and have identical strength, quality, purity, potency (and where applicable, other characteristics) as the RLD. [4]

19. A generic manufacturer (like a brand manufacturer) must also make "a full statement of the composition of such drug" to the FDA.[5] Additionally, in evaluating a drug product formulation

[1] https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations
[2] 21 U.S.C. § 355(j)
[3] § 355(j)(2)(A)(ii)
[4] *See, e.g.*, 21 C.F.R. 314.3(b),
[5] § 355(j)(2)(A)(iv) and § 355(b)(1)(C).

and inactive ingredients, a generic manufacturer must compare its generic drug to the RLD's formulation, not the formulation of the reference standard.

IV. POST APPROVAL CHANGES TO AN APPROVED ABBREVIATED NEW DRUG APPLICATION (ANDA) GENERALLY

20. The FDA has issued guidance entitled Changes to an Approved NDA or ANDA.[6] This Guidance is published to educate drug manufacturers as to the FDA's "current thinking" on this topic and provides guidance to drug manufacturers as to how to comply with the applicable statutes and regulations when making a change.

21. The Guidance sets forth that any time a holder of a NDA or ANDA intends to make a post-approval change to components and composition, manufacturing sites, manufacturing process, specifications, container closure system, and labeling the holder must assess the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a drug product. This is required as these factors relate to the safety of the drug product.

22. The FDA expects that changes involving the drug substance chemistry, manufacturing, and controls should include an evaluation of the potential risk impact associated with mutagenic impurities from changes to the route of synthesis, reagents, solvents, or process conditions after the starting material. Specifically, changes should be evaluated to determine whether the changes result in any new mutagenic impurities or higher acceptance criteria for existing mutagenic impurities. This includes an assessment of nitrosamine formation.[7]

23. These changes would include changes to vendors of raw materials, use of raw materials, route of synthesis, reagents, use of solvents (fresh or recovered), and/or any third-party vendors that are utilized for the manufacture of product.

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[6] Guidance for Industry, Changes to an Approved NDA or ANDA., US Dept of Health and Human Services, CDER, April 2004

[7] M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk, Guidance for Industry, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), May 2015, March 2018.

24. The FDA requires drug companies to continually assess all potential changes to their manufacturing processes because if these changes may result in, for instance, the formation of a new mutagenic or carcinogenic impurity in the product, it would impact whether the drug is the same as the RLD, in order to meet their duty of sameness.

V. NDMA AND NDEA ARE CARCINOGENIC AND MUTAGENIC COMPOUNDS

25. NDMA and NDEA are both nitrosamines. NDMA and NDEA (nitrosamines) are not new, nor unexpected impurities. The existence of such compounds and their potential toxicity is well known since the 1970s. Further, the link between nitrate/nitrites and nitrosamine formation, as well as their effects on human health, have been discussed widely in the popular media for decades.

26. Nitrosamines are organic compounds that feature a nitroso group (NO+) bonded to a nitrogen. The manner in which nitrosamines are formed is a matter of basic chemistry.

27. Nitrosamines are associated with a potential for significant carcinogenic risk and are part of the group of high potency mutagenic carcinogens referred to as the cohort of concern. [8]

28. The International Agency for Research on Cancer (IARC) states that both NDMA and NDEA should be regarded for practical purposes as if they were carcinogenic to humans. USEPA has rated both NDMA and NDEA as probable human carcinogens. The FDA also acknowledged that NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests.

29. Given the mutagenic and carcinogenic risk posed by these compounds, it is imperative that an assessment of potential for the presence of these mutagenic impurities take place when drugs are being developed and manufactured. This is also true for generic manufacturers who may utilize manufacturing processes that would create mutagenic impurities. DNA reactive substances like NDMA and NDEA can cause DNA damage when present at low levels which can lead to mutations and cause cancer. Any NDMA or NDEA in Valsartan API will directly carryover into the final drug product so it is imperative that impurities like these are detected and eliminated.

[8] M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals To Limit Potential Carcinogenic Risk, Guidance for Industry, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), May 2015, March 2018.

VI. VALSARTAN WHICH CONTAINED NDMA OR NDEA IN IT WAS NOT THE SAME AS THE BRANDED DIOVAN OR EXFORGE PRODUCTS

30. NDMA and NDEA are carcinogenic and should not be present in any drugs.

31. Defendants had an obligation to manufacture their products in such a way that they could assure the identity, strength, quality, and purity of their Valsartan containing products and could assure that their Valsartan containing products did not contain NDMA or NDEA.

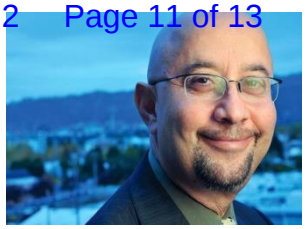
32. Valsartan containing products that contained NDMA and NDEA were not the generic equivalent of Diovan or Exforge because they contained NDMA and NDEA.

33. As a result, the Valsartan containing products with NDMA and NDEA were not the same as or chemically equivalent to the brand name Diovan or Exforge products because they contained NDMA and NDEA.

Dated: November 4, 2021

Ron Najafi, Ph.D.

Attachment A



RON NAJAFI

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EXPERIENCE

Najafi Pharma Inc., dba: Emery Pharma, Alameda, CA **2011-Present**
Founder, Chairman & CEO
Founded Emery Pharma as a subsidiary of NovaBay Pharmaceuticals in 2011. Established Najafi Pharma Inc. in 2015 and took Emery Pharma private in 2015 under Najafi Pharma Inc. umbrella. Established a new state-of-the art biological and chemical laboratory facility in Alameda, CA and relocated Emery Pharma there. Emery Pharma is a Contract Research Organization that delivers customized solutions to accelerate life science innovation. Our organization is FDA registered and inspected, DEA licensed, cGMP / GLP compliant. Emery Pharma focuses on pre-clinical support of early-stage biopharmaceutical companies around the globe. More on Emery Pharma at: www.emerypharma.com

NovaBay Pharmaceuticals, Inc. Emeryville, CA **2000-2015**
Founder, Chairman & CEO
Founded NovaBay Pharmaceuticals in December 2000 and took the company public in October of 2007. Raised a total of $100,000,000 through public and private investments and another $100,000,000 from non-dilutive sources such as corporate partnership with multi-national biopharmaceutical companies. Conducted multiple global clinical trials and helped establish several national and international partnerships in USA, Europe, China and Korea. Hired over 50 full-time pharmaceutical sales representatives, and established NovaBay's Avenova product as one of the fastest growing blepharitis treatments targeting meibomian gland dysfunction to treat chronic dry eye.

Highlighted achievements:

- Took company from seed stage to clinical stage to Initial Public Offering (IPO) in both the United States and Canada (October 2007) under the ticker symbol: NBY listed on NYSE and TSX
- Assembled a Board of Directors with significant strength in pharmaceutical industry and experience in early, mid and late-stage companies (2000-present)
- Formed Management Team with members who had significant managerial experience in major pharmaceutical companies. (2000-present)
- Led efforts in Chemistry Research and Development (until 2004)
- Developed Intellectual Property Base. Obtained initial US patent and filed 8 pending patents (2000-present)
- Led the effort in conducting multiple FDA clinical trials in USA, India, Brazil, Sri Lanka.
- Led the development of Avenova® and building a 50-person sales force in the United States
- Led the effort in the development of Auriclosene for urology (from concept to multiple successful FDA trial)
- Helped achieve significant breakthrough stabilization of NVC-101 and NVC-422 (2000-present)
- Key Publication in Peer reviewed Journal: Tetrahedron Letters 2008: Title: Remarkably Stable Chlorotaurine Derivative.
- Led financing efforts (Raised a total of $200 million from private, public, non-dilutive sources, nationally and internationally)
- Successfully completed financing of $15,000,000 privately and $20,000,000 Publicly

Key Partnerships

- Led effort in Partnering with Alcon Laboratories, Inc. with a total deal worth ~$100 million; $10 million upfront, $15 million in annual R&D funding.
- Led effort in Partnering with Alcon Laboratories, Inc. with a total deal worth ~$100 million; $10 million upfront, $15 million in annual R&D funding
- Led effort in Partnering with Kinetic Concepts, Inc., the leading wound care company (June 2007)
- Established a significant partnership with China Pioneer Pharma (now the largest NovaBay investors)
- Established a significant partnership with Shin Poong Pharma of Seoul – S. Korea
- Established a significant partnership with Galderma, S.A. the world leading dermatology company (March 2009)

R O N N A J A F I
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CP Lab Safety formerly known as California-Pacific Lab. Inc. Novato, CA **1996-2002**
Founder, President and CEO

- Formed company around environmental laboratory safety concept
- Obtained cost-effective manufacturing
- Built marketing, sales and distribution worldwide
- Broadened product offerings
- Developed Intellectual Property base

Achievements:

- CP Lab Safety was the recipient of the Congressional Certificate of Environmental Sustainability from Congressman Jared Huffman in recognition of the company's global effort and commitment to reducing environmental pollution (April 2016)
- Brought Manufacturing of the Ecological Funnels back to the United States (2007)
- Developed company to stage where it could be managed independently of founder
- Had several variations of initial concept developed
- Transferred manufacturing to offshore source dramatically reducing costs
- Built up direct marketing to major companies ensuring that product has regulatory mandate via US-EPA
- Established distribution through major scientific supply houses in the United States, Europe and Japan
- Built up environmental and safety catalog by adding products from third party manufacturers
- Obtained one issued and one pending patent. Obtained satisfactory six-figure settlement against copyright infringement by a major company

Applied Biosystems Division of Perkin-Elmer Corporation, San Francisco, CA **1993-1996**
Research Scientist

- Processed research and development of specialty phosphoramidites and their subsequent conversion to oligonucleotides (DNA).
- Developed methods for analysis of process impurities of phosphoramidites and oligonucleotides.
- Scaled up of the bench scale processes to the pilot plant.
- Invented protocols for purifying highly unstable phosphoramidites, precursors for DNA Synthesis.
- Selected as the outstanding scientist at Perkin-Elmer Applied Biosystems and the Recipient of Perkin-Elmer President's Award for Innovative Discoveries in Chemistry (September 1995).

Rhône-Poulenc Rorer Pharmaceutical, Department of Chemical Process R&D. Collegeville, PA **1991-1993**
Research Scientist

- Processed research and development of a series of next generation Asthma Drugs.
- Scaled up a hydroboration reaction from milligram to multi-kilogram quantity.
- Coordinated Process Chemistry with Pilot Plant and Analytical Group for testing and quality Control of synthesized drugs.
- Proposed and obtained approval to initiate a yearly Symposium called "Visions in Chemistry Symposium" at Rhone-Poulenc Rorer Pharmaceutical Company.
- Served as the co-chair and invited the first Symposium attendees: Professor H.C. Brown of Purdue University, recipient of 1979 Nobel Prize in Chemistry and six other well-known organoborane chemists to present at this symposium.

Aldrich Chemical Company Sheboygan Fall, WI **1989-1991**
Senior Development Chemist

- Led team of chemists responsible for research and development in the area of new products.
- Developed over 200 new products added to Aldrich catalog.
- Led a chemistry group in the area of organosilane-based reagents and synthetic intermediates.
- Conceived and designed a new version of Aldrich's patented "Oxford Sure Seal Cap" to improve its performance for highly unstable air-sensitive reagents.
- Synthesized drug candidates under Good Manufacturing Practice (GMP) protocol for use in animal / human trials.

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EDUCATION

University of California, Davis
Degree: Ph.D. in Organic Chemistry, December 1988.
Advisor: Professor George S. Zweifel.

UNIVERSITY OF SAN FRANCISCO
Degree: B.S. and M.S. in Organic Chemistry; June 1983.
Advisor: Professor John A. Soderquist.